REMARKS

Claims 19-25 are pending. Claims 1-18 are cancelled. Claims 19, 22 and 23 have been amended. The title and abstract of the application have been amended at the request of the Office. Support for these amendments can be found in the claims as originally filed. Reconsideration of the pending claims is respectfully requested.

Discussion of Rejection Under 35 U.S.C. § 102

The Examiner has rejected Claims 19-25 under 35 U.S.C. § 102(b) as being anticipated by claims 78-83 of Gurney (U.S. 2005/0196398 A1). To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

The Gurney application is not entitled to claim priority beyond April 5, 2004, which is the date when claims 78-83 were added to the Gurney application. These claims were added when the application was file. There is absolutely no support in the specification for a method of inhibiting APP metabolism by the administration of BACE2. Gurney, et al. all but admit this point when they filed their preliminary amendment by failing to point to any written support for claims 78-83 in the specification. Support for claims 105-109 was specified in the amendment, however.

It is not surprising that the Gurney application does not teach or suggest a method for reducing an amount of β-amyloid deposits comprising β-amyloid peptide (Aβ) from β-amyloid precursor protein (APP) using an effective amount of BACE2 or an agonist thereof. Gurney, et al considered Hu-Asp1, which is the terminology Gurney uses to describe BACE2, to be just another isoform of an APP degradation enzyme. See, e.g., paragraphs [0049] to [0051] of the Gurney application. As such, the absence of any support or implication that BACE2 actually inhibits APP degradation is consistent with Gurney et al's view that the BACE enzymes cause neural plaques and

not prevent them. Because the Gurney reference does not teach or suggest all the limitations of the claimed invention it does not anticipate the pending claims. For these reasons, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 102.

The Pending Claims are Fully Supported by the Specification

Claims 19-25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office also alleged that the subject matter of the pending claims was not supported by an enabling disclosure.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). In view of the *Union Oil of California* case, it is clear that an Applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000). Here, a number of formulations and modes of administration are clearly contemplated by the claimed invention. See, e.g., paragraphs [0081] to [0090]. Administration to the CNS is also clearly contemplated at paragraph [0148], which notes that BACE2 mRNA levels are low in brain tissue. This disclosure implies that administration of BACE2 to the brain, or other CNS tissue for that matter, would be advantageous. In view of this disclosure, one of ordinary skill in the art would have been motivated to administer BACE2 to the CNS.

The Office has also taken the position that the in vitro work reported in the specification is insufficient to enable the claimed invention. Applicants respectfully disagree. Use of BACE2 to inhibit Aβ levels in neuronal SKN cells is sufficient data to enable the present claims. Moreover, routes of administration to the CNS were well known at the time the present application was filed. For example, Pain, et al., performed intracerebroventricular administration of 192 IgG-Saporin in rats to study the effect of this toxin. Br J Anaesth. (2000) 85(6):869-73 (a copy of which is

provided as Exhibit A). This work demonstrates that administration of molecules much larger than that of BACE2 was being practiced by those of ordinary skill in the art at the time the present application was filed. In view of the data provided as well as the provided references, Applicants submit that the pending claims are adequately supported by an enabling disclosure. As such, the present rejection should be withdrawn.

The Pending Claims are Definite and Particular

The Office rejected the pending claims under 35 U.S.C. § 112, second paragraph for using the definite article in claims 19, 22 and 23 without formal antecedent basis. These claims have been amended to address this issue.

Title and Abstract

The Office objected to the title and the abstract of the specification. Both have been amended to clarify the subject matter recited therein.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing Docket No. 219002030710.

Dated: March 9, 2006

Respectfully submitted,

By _____

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